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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,074	07/30/2003	David R. Milich	VACCINE-07971	9330

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EXAMINER	
BROWN, TIMOTHY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,074	MILICH ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

8-0-0

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 9-11, 13-16, 19 and 20, drawn to a composition comprising a heterologous antigen linked to the polypeptide represented by SEQ ID NO:58, wherein said polypeptide comprises a loop region and wherein said antigen is inserted at a position outside the loop region, classified in class 424, subclass 189.1.

II. Claim 5, drawn to a composition comprising a heterologous antigen linked to the polypeptide represented by SEQ ID NO:58, wherein said polypeptide comprises a loop region having from 1 to 100 amino acids substituted in the C-terminal region commencing at residue I^{149}, and further comprising at least one immune enhancer sequence, classified in class 424, subclass 189.1.

III. Claims 6-8, drawn to a composition comprising a heterologous antigen linked to the polypeptide represented by SEQ ID NO:58, wherein said polypeptide comprises a loop region, and wherein said antigen is inserted at a position within the loop region, classified in class 424, subclass 189.1.

IV. Claim 12, drawn to a composition comprising a heterologous antigen linked to the polypeptide represented by SEQ ID NO:58, wherein said polypeptide comprises a loop region, and wherein said antigen is inserted at a position within the loop region, and outside the loop region, classified in class 424, subclass 189.1.

V. Claims 17 drawn to a nucleic acid sequence that encodes a heterologous antigen linked to the polypeptide represented by SEQ ID NO:58, wherein said polypeptide comprises a loop region having from 1 to 100 amino acids substituted in the C-terminal region commencing at residue I^{149}, classified in class 536, subclass 23.72.

VI. Claim 18, drawn to an expression vector that encodes a heterologous antigen linked to the polypeptide represented by SEQ ID NO:58, wherein said polypeptide comprises a loop region having from 1 to 100 amino acids substituted in the C-terminal region commencing at residue I^{149}, classified in class 424, subclass 93.2.

VII. Claims 21-24, drawn to a method for inducing an immune response, classified in class 424, subclass 227.1.

VIII. Claims 25-30, drawn to a method for manufacturing an immunogenic composition, classified in class 435, subclass 69.3.

The inventions are distinct, each from the other for the following reasons:

Inventions I and II are unrelated to Invention III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this case, Inventions I and III are each drawn to a distinct antigenic polypeptide that is defined by a unique conformation and/or amino acid sequence. These differences provide the antigenic peptides with specific immunological reactivities. Moreover, the specification does not disclose

using the particular polypeptides of Inventions I and II in any combination with Invention III. Thus, Inventions I and II are unrelated to Invention III due to different effects.

Invention I and II are related as combination/subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In this case, the combination (Invention II) does not rely on the particulars of the subcombination (Invention I) for patentability. This results because the combination is generally drawn to a antigenic polypeptide and an one immune enhancer sequence, while the antigenic polypeptide of the subcombination is drawn to specific antigenic sequences. The subcombination of Invention I also has its own distinct utility as an antigenic substance. For at least these reasons, Inventions I and II may be restricted as combination/subcombination.

Inventions I and III are related to Invention IV as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In this case, the subcombination (i.e. Invention I) has utility that is separate from the combination in that a polypeptide comprising an antigen inserted within, or outside, the loop region may be used as antigenic substance, or on a column to capture antibody.

Inventions I-IV are unrelated to Inventions V and VI. As noted above, inventions are unrelated if they are show to have different effects. In this case, Inventions I-IV each comprise an antigenic polypeptide. The effect of Inventions I-IV is therefore inducing a specific

immunological response. Inventions V and VI comprise a nucleic acid capable of transforming a host. Based on their different effects, Inventions I-IV are unrelated to Inventions V and VI. Note that Inventions V and VI are unrelated to one another due to their different effects; Invention V functions as a hybridization probe while Invention VI functions as a transformation vector.

Inventions I-IV are related to Invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Here, the polypeptides of Invention I-IV can be used diagnostically, or as a means for purifying antibody. This is a materially different process than Invention VII's method of inducing an immune response. Inventions I-IV are therefore distinct from Invention VII.

Invention VIII is related to Inventions I-IV as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In this case, the product of Inventions I-IV can be produced by a materially different process in that antigenic polypeptides can be made through solid phase protein synthesis. Inventions I-IV are therefore distinct from Invention VIII.

Inventions V and VI are unrelated due to different effects. This follows because the polynucleotide of Invention V may be used as a hybridization probe for detecting a gene.

Invention VI on the other hand is drawn to an expression vector that is capable of transforming a host. Inventions V and VI are therefore unrelated due to their different effects.

Inventions V and VI are unrelated to Invention VII's method of inducing an immune response. This results because Invention VII relies on the administration of an antigenic polypeptide and not the polynucleotides of Inventions V and VI. Moreover, Inventions V and VI function as a hybridization probe and transforming agent respectively. Thus, Inventions V and VI are unrelated to Invention VII due to different effects.

Invention V and VI are related to Invention VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this case, Invention V can be used in a materially different process than Invention VIII's method of manufacturing an antigenic polypeptide in that the polynucleotide of Invention V can be used as a hybridization probe. Invention VIII can also be used in a materially different process since its vector can be applied to an assay for detecting the transformation of a host.

Finally, Invention VII is unrelated to Invention VIII due to different modes of operation. This results because Invention VII relies on the administration of an antigenic polypeptide, while Invention VII involves the step of transforming a host with a heterologous polynucleotide.

Invention I is drawn to a generic antigenic polynucleotide which includes the patentably distinct species listed below. An election of Invention I therefore requires an election of no more than three of the following species:

i) R^{150}

ii) K^{150}

iii) A^{150}

iv) R^{150} $R^{151}C^{152}$

v) SEQ ID NO:3

vi) SEQ ID NO:4

vii) SEQ ID NO:5

viii) SEQ ID NO:6

ix) SEQ ID NO:43

x) SEQ ID NO:44

xi) SEQ ID NO:45

xii) SEQ ID NO:46

xiii) SEQ ID NO:47

xiv) SEQ ID NO:48

xv) SEQ ID NO:49

xvi) SEQ ID NO:50

xvii) SEQ ID NO:51

xviii) SEQ ID NO:52

xix) SEQ ID NO:53

xx) SEQ ID NO:54

xxi) SEQ ID NO:55

xxii) SEQ ID NO:56

xxiii) SEQ ID NO:2

xxiv) SEQ ID NO:7

xxv) SEQ ID NO:8

xxvi) SEQ ID NO:9

xxvii) SEQ ID NO:10

xxviii) SEQ ID NO:11

xxix) SEQ ID NO:12

xxx) SEQ ID NO:13

xxxi) SEQ ID NO:14

xxxii) SEQ ID NO:15

xxxiii) SEQ ID NO:16

xxxiv) SEQ ID NO:17

xxxv) SEQ ID NO:18

xxxvi) SEQ ID NO:19

xxxvii) SEQ ID NO:20

xxxviii) SEQ ID NO:22

xxxix) SEQ ID NO:23

xl) SEQ ID NO:24

xli) SEQ ID NO:25

xlii) SEQ ID NO:26

xliii) SEQ ID NO:27

xliv) SEQ ID NO:28

xlv) SEQ ID NO:29

xlvi) SEQ ID NO:30

xlvii) SEQ ID NO:31

xlviii) SEQ ID NO:32

xlix) SEQ ID NO:33

l) SEQ ID NO:34

li) SEQ ID NO:35

lii) SEQ ID NO:36

liii) Position 71

liv) Position 72

lv) Position 73

lvi) Position 74

lvii) Position 75

lviii) Position 83

lix) Position 84

lx) Position 85

lxi) Position 92

lxii) Position 44

The species appearing above are distinct, each from the other, because they are unrelated. Each of these species comprises an antigenic polypeptide that has its own unique amino acid sequence and immunogenicity. Thus, the listed species of polypeptides are unrelated due to different effects.

Applicant is required under 35 U.S.C. 121 to elect no more than three disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

JAMES HOUSEL 6/13/05
SUPERVISORY PATENT EXAMINER
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TMB 6/7/05